B. Kristian W. Rasmussen, III, FL Bar No. 0229430
LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.
316 South Baylen Street, Suite 600 (32502)
P. O. Box 12308
Pensacola, Florida 32591
Telephone: (850) 435-7080
Facsimile: (850) 435-7020

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

In re: Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation	**MDL No. 1699** **District Judge: Charles R. Breyer** **Magistrate:**

C 07 [illegible] 7 CRB

DANIEL FARRIER, individually, Plaintiff, v. PFIZER, INC., PHARMACIA CORP., and G.D. SEARLE & CO., Defendants.	Case No. _____ **CIVIL COMPLAINT** **JURY TRIAL DEMANDED**

DANIEL FARRIER, individually, Plaintiff, by and through counsel, brings this action against Defendants PFIZER, INC., PHARMACIA CORP., and G.D. SEARLE & CO. (hereafter "Defendants") and alleges as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medication celecoxib, trade name CELEBREX® ("Celebrex").

2. Plaintiff is, and was at all relevant times, an adult resident citizen of the State of Oklahoma residing at 2908 SE 96th Street, Moore, OK 73160.

3. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York, New York. In 2003, Pfizer acquired Pharmacia for nearly $60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug celecoxib, under the trade name Celebrex in Oklahoma, and nationwide.

4. Defendant Searle ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Celebrex nationwide and in Oklahoma. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

5. Defendant Pharmacia ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling Celebrex nationwide and in Oklahoma.

6. Celebrex was developed by Pharmacia Corp. ("Pharmacia"). Searle and Pharmacia are now both subsidiaries of Pfizer Inc. ("Pfizer").

II. JURISDICTION AND VENUE

7. This is an action for damages, which exceeds seventy-five thousand dollars ($75,000.00).

8. There is complete diversity of citizenship between the Plaintiff and Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00, and because there is complete diversity of citizenship between Plaintiff and Defendants.

9. This Claim is filed in the Northern District of California pursuant to MDL-1699, Pretrial Order No. 2. Venue is proper in this Western District of Oklahoma ("the District") pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in the district, thereby receiving substantial financial benefit and profits the dangerous

product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

10. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, Celebrex. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce the aforementioned prescription drug. Defendants do substantial business in the District and advertise in the District, receive substantial compensation and profits from sales of Celebrex in the District, and made material omissions and misrepresentations and breaches of warranties in the District so as to subject them to *in personam* jurisdiction in the District. In engaging in the conduct alleged herein each defendant acted as the agent for each of the other defendants, or those defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

11. Assignment to the San Francisco Division is proper as this action is related to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. (See also, MDL-1699 Pretrial Order No. 2)

IV. FACTUAL BACKGROUND

A. Facts Regarding Plaintiff

12. Plaintiff was prescribed, and began taking, Celebrex on or about May 10, 2006.

13. On or about May 14, 2006, as a direct and proximate result of using Celebrex, Plaintiff suffered a severe, life-threatening reaction known as Toxic Epidermal Necrolysis (TEN) or Stevens Johnson Syndrome (SJS), collectively (TEN/SJS). (Hereinafter "TEN/SJS reaction" or "the Reaction".)

14. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's use of Celebrex and TEN/SJS unaware—and could not have reasonably known or have learned through reasonable diligence—that such reaction directly resulted from Defendants' negligent

and otherwise culpable acts, omissions, and misrepresentations or from Plaintiff's ingestion of Celebrex.

15. Plaintiff used Celebrex in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

16. Plaintiff would not have used Celebrex had Defendants properly disclosed the risks associated with the drug.

17. The Reaction is life threatening. The Reaction caused the Plaintiff to suffer severe and permanent injury and damages as set forth herein; and, places the Plaintiff at risk of further serious injury or death.

18. The Plaintiff's injuries have resulted in an incredible ordeal marked by continued months of care and treatment. To date, the Plaintiff requires a doctor's care regularly to treat his permanent and continuing injuries. The Reaction and resulting injuries were caused by Plaintiff's ingestion of dangerous product Celebrex.

19. Plaintiff was not aware —and could not have reasonably known or have learned through reasonable diligence—that his injuries and damages directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and misrepresentations or from his ingestion and/or use of Celebrex.

20. The Defendants knew, should have known, or could have learned through reasonable diligence that the Reaction and resulting injuries could have and did directly result from Plaintiff's ingestion of Celebrex.

21. Plaintiff would not have purchased and used Celebrex had the Defendant properly disclosed the risks associated with the drug, including the risk of experiencing TEN, EM and/or SJS.

22. As a result of the Defendant's failure to warn about the serious and potentially life-threatening effects, Plaintiff sustained the permanent injuries and damages as herein alleged.

23. As a direct and proximate result of Defendant's negligence willful, wanton and otherwise culpable acts as described herein, the Plaintiff has sustained permanent injuries and damages. These injuries and damages have caused, and will continue to cause, extensive pain and suffering and severe emotional distress, and have substantially reduced Plaintiff's ability to enjoy life; and have caused, and will continue to cause, Plaintiff to expend substantial sums of money for medical, hospital, and related care, all to Plaintiff's general damage. Upon information and belief, the Plaintiff will be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained

B. Facts Regarding Celebrex: Science and other Cox-2 Inhibitors

24. Celebrex is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs. More specifically, and unlike traditional NSAIDs, Celebrex is a Cox-2 inhibitor similar to Bextra and Vioxx.

25. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

26. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

27. Prostaglandin I2 is the predominant cyclooxygenase product in endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2 is a potent platelet aggregator and vasoconstrictor which is synthesized by

platelets. Therefore, while the older NSAIDS suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

28. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

29. Defendants and other pharmaceutical companies set out to remedy these ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing inflammation.

30. In making this decision, Defendants and their predecessors in interest either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels and causes thromboxane A_2 to be uninhibited, causing blood clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke, unstable angina. The vasoconstriction and fluid retention cause the hypertension.

31. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in January 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new "blockbuster" drug over less inexpensive NSAIDs. In May, 1999, Merck & Co., Inc. ("Merck") launched Vioxx, its own selective COX-2 inhibitor.

32. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a "second generation" selective COX-2 inhibitor and filed for FDA approval of Valdecoxib (Bextra) on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

C. Facts Regarding Celebrex

33. Celebrex is a prescriptive drug in the nonsteroidal anti-inflammatory drug (NSAID) class of drugs and specifically the Cox-2 "selective" family.

34. Celebrex was marketed in the United States for the treatment of osteoarthritis (OA) and adult rheumatoid arthritis (RA).

35. Celebrex was only approved in the U.S. for the treatment of OA and RA.

36. Celebrex, like other NSAIDs in its class, is used for the relief of pain and inflammation associated with OA and RA. NSAID drugs are believed to exert their pharmacological effects through inhibition of the enzyme cyclooxygenase (Cox). Scientists have identified two Cox isomers: "Cox-1" and "Cox-2." The prostaglandins produced by Cox-1 play a key role in platelet aggregation. Although Cox-2 is responsible for the synthesis of mediators of pain, inflammation and fever, it plays a physiological role in a number of tissues including the female reproductive tract, the kidney, and vascular endothelium. All NSAIDs inhibit both Cox isomers, but to varying degrees. At therapeutic doses, drugs that are Cox-2 preferential and/or selective (i.e. Celebrex and Mobic which are similar to Cox-2 inhibitors like Bextra and Vioxx) do not inhibit Cox-1.

37. In theory, the Cox-2 selectivity should result in a significantly lower incidence of gastrointestinal ulceration than traditional NSAIDs. That is, Cox-2 drugs were not developed to be a miracle pain reliever, but rather as a pain reliever that could be tolerated by consumers with sensitive stomachs. Thus, Cox-2 inhibitors were developed to treat joint pain and inflammation for those members of the population who could not tolerate traditional anti-inflammatories (e.g. aspirin, Naproxen, Aleve, ibuprofen).

38. During the mid and late 1990's, pharmaceutical researchers, scientists and companies were engaged in a "race" or competition to develop pain relievers which were safer on the gastrointestinal system. Thus, Celebrex was developed and marketed. Celebrex was released onto the open market before adequate studies had been performed or research conducted.

39. The Celebrex drug label does not adequately warn for TEN, EM, or SJS. In fact, until July 31, 2005 the drug label contained no warning and made no mention whatsoever of TEN/SJS reactions.

D. Facts Regarding the Reaction: TEN/EM is a Catastrophic, Life-Threatening Reaction

40. As a result of his ingestion of Celebrex, Plaintiff suffered the terrible reaction know as Toxic Epidermal Necrolysis ("TEN"), which is akin to Erythema Multiforme (major) ("EM") a.k.a. Stevens Johnson Syndrome (SJS) – hereinafter "The Reaction". The Reaction is life threatening; the mortality rate associated with EM and TEN is 30% to 70%.[1] The Reaction is characterized by, and the Plaintiff suffered from, inflammation of the mucous membranes of the mouth, throat, eyelids and anogenital region. Affected individuals, including the Plaintiff, develop lesions of the skin and mucous membranes that are red and dark in color. In some cases, like the Plaintiff's case, these lesions turn into painful blisters similar to burns. These blisters can spread to the face, abdomen, back, legs and hands. Abnormalities of the eyes can develop as well; these abnormalities include infection of the delicate membrane of the eye and eyelids (conjunctiva) and inflammation associated with an abnormal discharge from the conjunctiva. Complications can include: permanent blindness, dry-eye syndrome, photophobia, lung damage, chronic obstructive pulmonary disease (COPD), asthma, permanent loss of nail beds, scarring of the esophagus and other mucous membranes, arthritis, and chronic fatigue syndrome. Many patients' pores scar shut, causing them to retain heat. These are just some of the side effects that have been reported.[2]

E. The Defendant knew or should have known that Celebrex caused TEN, EM and/or SJS ("the Reaction").

41. The Defendant had information from many sources indicating that Celebrex greatly increased the probability of causing the Reaction; including: a) medical literature, b) clinical trial data, and c) adverse event reports.

---

[1] The Boby R. Alford Dept. of Otorhinolaryngology, *Erythema Multiforme and Toxic Epidermal Necrolysis*, Feb. 20, 1992. www.bcm.tmc.edu/oto/grand/22092.html. at page 2 of 6.

[2] See generally, The Stevens Johnson Syndrome Foundation at www.sjssupport.org.

42. Despite the medical literature proving the link between NSAIDs and the Reaction the Defendant: a) failed to warn prescribing physicians, consumers and the Plaintiff of the increased risk of experiencing the Reaction; b) failed to adequately warn prescribing physicians, consumers, and the plaintiff of the increased risk of experiencing the Reaction; c) failed to conduct pre-market clinical trials and studies of the drug; d) failed to implement sufficient post marketing surveillance and/or pharmacoviglience programs to monitor and report adverse events associated with the drug; physicians; and e) failed to adequately collect, analyze and report the number and percentage of adverse events. The Defendant did not adequately study the drug, Celebrex prior to market launch; nor implement an adequate surveillance and/or pharmacovigilance program to monitor the adverse events after Celebrex was sold on the open market. The available medical literature, noting the strong link between NSAIDs and the Reaction alone should have been sufficient to cause the Defendant to conduct adequate studies and/or implement adequate post marketing surveillance measures and pharmacovigilance program.

43. On February 20, 1992, Dr. Michael G. Stewart, reported the results of his studies relating to the causes of Erythema Multiforme (EM) and Toxic Epidermal Necrolysis (TEN).[3] (Note: Many authors use the designation EM minor and major -- EM minor referring to lesions only and EM major being synonymous with Stevens-Johnson Syndrome (SJS). Dr. Stewart specifically reported the following: "Medications are reported as the most common probable etiologic factor in [EM] and TEN. Antibiotics are reported to cause as least 30% to 40% of cases, with sulfonamides, tetracyclines, amoxicillin, and ampicillin most commonly implicated. Nonsteroidal anti-inflammatory [NSAID's] medications are also implicated ..."[4]

44. In 1984, the *Journal of the American Medical Association* reported that NSAIDs were widely used in the United States and were a "frequent cause of cutaneous reactions" including TEN and EM (SJS).[5] Similarly, in 1988, the results of a Danish survey were

---

[3] The Boby R. Alford Dept. of Otorhinolaryngology, *Erythema Multiforme and Toxic Epidermal Necrolysis*, Feb. 20, 1992. www.bcm.tmc.edu/oto/grand/22092.html.

[4] Id. at 2 of 6.

[5] JAMA Vol. 252 No. 11, September 21, 1984.

published.[6] The survey reviewed 17 years of data and confirmed the association of NSAIDs causing TEN and EM (SJS).

45. On December 14, 1995, *The New England Journal of Medicine* reported the results of several studies related to *Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis.*[7] The article opens noting that TEN and SJS are "life-threatening, drug induced cutaneous reactions." The *NEJM* article reports that sulfonamides are among the drugs most "consistently associated" with SJS and TEN and the association of NSAIDs "is controversial."[8] The studies evaluated in the article confirm "that the use of antibacterial sulfonamides, oxicam NSAID's, chlormezanone, anticonvulsant agents, and allopurinol [are] associated with substantial relative increase in the risk of toxic epidermal necrolysis and Stevens-Johnson Syndrome."[9] NSAIDs are "associated with a large increase in the risk of Stevens-Johnson Syndrome or toxic epidermal necrolysis."[10]

46. In 2001, *Pharmacological Reviews* reported the association of NSAIDs with cutaneous drug eruptions.[11] The review reports the results of a "survey of drug eruption in France from 1981 to 1985 [which] found that NSAIDs had emerged as the more common cause of TEN."[12] The Review notes the results of another study (Alanko et. al.) from 1989, which "found NSAIDs to be the causative agent in 27% of all adverse drug eruptions."[13] Finally, and importantly, the Review notes: "Pseudoporphyria [cutaneous drug eruption] has been reported in association with several of the newer NSAIDs."[14]

47. In January 2002, *Pediatrics* reported the "Long-Term Consequences of Toxic Epidermal Necrolysis in Children."[15] The article reports on the historical association

---

[6] PMID, Dan Med Bull. 1998 Apr., 35(2):187-192.
[7] N ENG J MED 1995;333:1600-7.
[8] Id.
[9] Id. at 1604.
[10] Id.
[11] *Pharmacological Reviews*: Vol. 53, Issue 3, 357 – 379, September 2001.
[12] Id. at 8 of 27.
[13] Id. at 27 of 27.
[14] Id. at 27 of 27
[15] *Pediatrics* Vol. 109 No. 1 January 2002.

between pharmaceutical drugs and TEN/SJS and notes the "mortality rate as high as 70%; death usually results from sepsis or organ failure."[16]

48. In 2002, the *Journal of Dermatology Online* reported sulfonamides as one of the most frequent "culprit drugs" associated with SJS and TEN.[17] The same journal article notes, "survivors of TEN/SJS should not be re-exposed to the suspected offending agent(s) or to related compounds. For example, cross-reactions have been reported between different anticonvulsant agents or non-steroidal anti-inflammatory drugs."[18]

49. In 2003 a group of respected dermatologists and epidemiologists conducted an internal case-control study to evaluate the relative increase in risk of experiencing a TEN/SJS reaction with use of ibuprofen. The results were alarming and statistically significant: ibuprofen use increased the risk by a factor of 5.5.[19] That is, ibuprofen consumers were 5.5 times more likely to have a TEN/SJS reaction.

50. In 2003, *The Journal of Rheumatology* reported on the risks of SJS and TEN associated with NSAIDs. The introductory paragraph cites six journal articles dating back to 1984 linking NSAIDs with SJS and TEN.[20] The article concludes: "Given the high frequency of use of these medications [NSAIDs] … different reaction rates are strong evidence that at least some NSAIDs are true risk factors for the development of SJS and TEN."[21]

51. In 2003, the SJS Foundation reported "numerous" TEN/SJS reactions" after consuming an NSAID.[22]

52. On January 6, 2004, the FDA, in a letter responding to the increased number of TEN/SJS events reported "in children from the use of ibuprofen'" wrote: "SJS is a well-recognized, rare adverse event of all [NSAIDs] which includes ibuprofen.[23]

---

[16] Id. at 74.
[17] Dermatol Online J 8(1):5, 2002.
[18] Id. at 9 of 15.
[19] Mockenhaupt, et. al. 2003.
[20] *The Journal of Rheumatology* 2003; 30:10
[21] *The Journal of Rheumatology* 2003; 30:10 at 2238
[22] Stevens Johnson Syndrome Foundation: Letter to FDA; January 26, 2005.
[23] FDA DHHS: Letter to SJS Foundation; January 6, 2004.

53. In 2004 the SJS Foundation reportedly received notice that 12 children suffered TEN/SJS reactions after consuming OTC NSAIDs.[24]

54. In 2005, within the first two weeks of the year, the SJS foundation reported that it had received of two children being hospitalized with a TEN/SJS reaction after consuming an OTC NSAID.[25] On January 26, 2005 the Stevens Johnson Syndrome Foundation, in a letter to the FDA, reported their concern over the link between TEN/SJS and Children's Motrin. According to the SJS Foundation, in 2005, it had "more reports of SJS [linked] to ibuprofen than Bextra, yet Bextra warrants a black box warning."

55. On February 15, 2005 a Citizen Petition was filed with the FDA ("The Petition").[26] The Petition, reported the results of critical safety information related to the increased risk of TEN/SJS reactions with the use of ibuprofen. The Petition opens noting that the "increased risk of [TEN/SJS] associated with ibuprofen has been established in the scientific literature since 1978 through the present."[27]

F. Defendant's Knowledge From Other Similar Drugs.

56. Pursuant to 21 CFR 10.30, Roger E. Salisbury, M.D., Chief Professor of Plastic Surgery at the New York Medical College, along with others, submitted a Citizen Petition to the FDA in 2005 on behalf of themselves and several TEN/SJS victims and their families.[28] Specifically, the petition requested the FDA to conduct an assessment of necessary additions to the over-the-counter label for ibuprofen products. The petition stated that scientific literature, dating back as early as 1978, has established an association between ibuprofen and TEN/SJS.[29] Further, it stated that other drugs, specifically Zithromax, explicitly carry a TEN/SJS warning while indicating a lower relative risk for such reactions than that of ibuprofen.[30] The authors of

---

[24] Stevens Johnson Syndrome Foundation: Letter to FDA; January 26, 2005.
[25] Stevens Johnson Syndrome Foundation: Letter to FDA; January 26, 2005.
[26] USDHHS Citizen Petition: Docket No. 2005P-0072.
[27] Id. at 1.
[28] FDA Docket No. 2005P.0072; Feb. 15, 2005
[29] Id. at 1 of 25
[30] Id. at 4 of 25

the petition claimed that, given such information, the current prescription labeling for ibuprofen products is thus in violation of 21 CFR 201.57.[31] Additionally, the petition claimed that McNeil markets similar products abroad with more in depth warnings regarding TEN/SJS symptoms than those of domestic products. Specifically, the authors discuss Dolormin, a McNeil ibuprofen product marketed in Germany, as a non-prescription drug with such additional warnings.[32]

57. In January of 2005, Jean Farrel McCawley, Director of the Stevens Johnson Syndrome Foundation ("SJS Foundation"), wrote a letter to the FDA regarding the association between NSAIDs and TEN/SJS.[33] Specifically, Ms. McCawley stated that the SJS Foundation has received more reported TEN/SJS cases associated with ibuprofen than Bextra.[34] Additionally, the letter noted that while Bextra contained a box label warning of such potential associations, ibuprofen products did not.[35] (The FDA removed Bextra in January 2005, the FDA asked Pfizer to remove Bextra from the market and advised that it would initiate involuntary withdrawal proceeding if Pfizer did not remove Bextra voluntarily.) The SJS Foundation reported that the number of TEN/SJS cases associated with NSAIDs is expected to dramatically rise.[36] Thus, the problem continues to worsen. The letter concluded by pleading that the FDA require ibuprofen products to contain a black box warning regarding associated TEN/SJS risks.[37]

G. Celebrex Label

58. Celebrex has only been approved to the "signs and symptoms of osteoarthritis and rheumatoid arthritis." See generally, Celebrex labels, *Indications and Usage*.

59. The original label contained no warning whatsoever of TEN, EM, SJS or severe skin reaction of any kind. Specifically, the label omitted any reference to SJS, EM, and/or TEN in the Contraindications, Warnings, and Precautions. The label only references rash and TEN/EM in the Adverse Reactions section.

---

[31] Id. at 3 0f 25
[32] Id. at 18 of 25
[33] SJS Foundation letter to FDA; January, 26 2005
[34] Id.
[35] Id.
[36] Id.
[37] Id.

60. In April 2005, the FDA required all manufacturers of prescription NSAIDs to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. During the same announcement, the FDA required all manufacturers of over-the-counter (OTC) Non-Selective NSAIDs (e.g. Motrin, Advil, Aleve, etc.) to warn about the potential skin reactions. Interestingly, the FDA announcement notes that "Long-term controlled clinical trials have not been conducted with most of these NSAIDs." Id. at 3 of 5. Celebrex is one of the drugs subjected in inadequate study prior to market launch.

61. The Medication Guide referenced in the 2005 FDA announcement, which applies to Celebrex required the following warnings for all OTC NSAIDs: "***life-threatening skin reactions and life-threatening allergic reactions***" as possible side effects of NSAID use. Celebrex is listed as one of the culprit NSAIDs. *Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).*

62. On April 7, 2005, the FDA published the following: 1) Press Release, 2) "Public Health Advisory", 3) "Drug Information Page" and 4) responded to frequently asked questions about its actions with an interned "Questions and Answers" web page.[38]

63. Despite the unjustifiable delay in providing any information to consumers warning them of the potential life threatening reaction, if the Defendant had only acted responsibly prior to the April 7, 2005 FDA announcements the Plaintiff may have been spared this horrendous reaction. Specifically the FDA required the following:

H. Warnings Were Inadequate and Could Have Been Changed Anytime

1. Labeling Requirements

64. According to federal regulations, prescription drug labels must "contain a summary of the essential scientific information needed for safe and effective use." The label "shall be informative and accurate and neither promotional in tone nor false and misleading …." See generally, 21 C.F.R. § 201.56. Furthermore, every drug label must "contain specific information required under § 201.57 under certain headings, including in this order: Contraindication, Warnings, Precautions, Adverse Reactions.

[38] www.fda.gov/medwatch/safety/2005/safety05.htm

65. More specifically, § 201.57 requires the following information in each of the four respective sections:

> 1) Contraindications: "Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it …" Id. at § 201.57(d)
>
> 2) Warnings: "Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. ..." Id. at § 201.57(e)
>
> 3) Precautions: "This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug. Id. at § 201.57(f)(1)
>
> 4) Adverse Reactions: "An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." ***For clarification the section further reads: "The 'Warnings' section of the labeling or, if appropriate, the 'Contraindications' section of the labeling shall identify any potentially fatal adverse reaction***." 21 C.F.R. 201.57 (g), Emphasis supplied.

66. The information provided in the Celebrex label is insufficient.

2. The Defendant Could Have Strengthened the Label Anytime Unilaterally

67. The Defendant were negligent, and/or acted with willful, wanton and gross disregard for human life in that they could have strengthened the information in the respective drug labels unilaterally, without prior approval from the Food and Drug Administration (FDA). See generally, *Witczak v. GSK*, 377 F.Supp.2d 729 (2005) interpreting 21 C.F.R. § 314.70(c)(6)(iii)(A).

68. FDA regulations explicitly permit drug manufacturers to unilaterally strengthen its warning label at any time without regulatory pre-approval. 21 C.F.R. § 314.70(c)(6)(iii)(A). This particular regulation was promulgated precisely to allow drug-makers to quickly strengthen label warnings when evidence of new side effects are discovered. *See* 30 Fed.Reg. 993 (Jan. 30, 1965). Thus, the regulation "permits the addition to the drug's labeling or advertising of information about a hazard without advance approval" by the FDA. 44 Fed.Reg. 37447 (June 26, 1979); See also, *Witczak v. GSK*, 377 F.Supp.2d 726, 729 (2005).

H. Facts and Allegations Regarding the Defendant and Celebrex

69. The Defendant, knew or should have known that Celebrex, when used alone or in combination with other drugs, created significant risks of serious injuries or disorders, including TEN, EM, and/or SJS, and related complications, as to which the Defendant failed to make proper, reasonable or adequate warning to the public and physicians about the risks associated with the use of their product.

70. At all times material hereto, the Defendant knew or should have known of the dangerous, life threatening risks associated with the use of Celebrex.

71. At all times material hereto, the Defendant proceeded to or permitted their respective drugs to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious side effects and dangerous, life threatening risks.

72. The Defendant failed to adequately warn the Plaintiff, and other consumers, of the potential serious dangers which they knew or should have known might result from consuming its respective drugs.

73. The Defendant failed to properly warn physicians through the package insert for Celebrex, regarding the catastrophic, potentially fatal, reaction known as TEN and/or SJS.

74. In fact, the information in the Celebrex label downplayed the risk of TEN and/or SJS by burying such information in the "Adverse Reactions" section of the label. Even then no specific mention of TEN or SJS is made.

75. The Defendant failure to include warnings regarding the risks of TEN, EM, and/or SJS was made with full knowledge of such risks. The Defendant were aware of published medical literature since which demonstrated a causal relationship between antibiotics and the

Reaction.

76. The Celebrex package insert is inadequate in warning of the risks of TEN and/or SJS, as it makes no mention of TEN, EM or SJS or any dermatological reactions at all in the "Warnings" section.

77. The Celebrex package insert is inadequate in warning of the risks of TEN and/or SJS, as it makes no mention of TEN, EM, or SJS at all in the "Precautions" section of the label.

78. As a result of the manufacturing and marketing of their respective drugs, have reaped huge profits; while failing to adequately warn of the potential hazard associated with the ingestion.

79. Prior to the manufacturing, sale and distribution of their respective drugs, the Defendant, through their respective officers, directors and managing agents, had notice and knowledge from several sources, that the products presented substantial and unreasonable risks of harm to the patients. As such, patients, including Plaintiff, were unreasonably subjected to risk of injury or death.

80. Despite such knowledge, the Defendant, through their respective officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to properly warn the Plaintiff, patients, consumers and the public of the serious risk of injury occasioned by the known propensity to cause SJS, TENS and similar reactions.

81. The Defendant and their respective officers, agents and managers intentionally proceeded with the manufacturing, sale and marketing of their respective drugs, knowing that patients and consumers would be exposed to serious danger; specifically, the life threatening reaction TEN, EM, or SJS.

82. The tortuous actions and misdeeds of the Defendant as alleged herein are ongoing and at all times relevant hereto were ongoing and continuous and constituted ongoing and continuous torts.

83. The Defendant sold their respective drugs by misleading users about the product and by failing to adequately warn the users of the potential serious dangers, which they knew or should have known, might result from consuming their respective drugs. The Defendant widely and successfully marketed their respective drugs, throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of their respective drugs, in order to induce widespread use and consumption. The Defendant made misrepresentations by means including but not limited to: media advertisements, and statements contained in sales literature

I. Facts Regarding Other Celebrex's Safety and Risk

84. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the market launch. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Celebrex, Defendants was aware that, by inhibiting COX-2, Celebrex altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954.

85. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as Celebrex, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

86. Based on the studies performed on Celebrex, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants

knew when Celebrex was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2 inhibitors, including Celebrex, decrease blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

87. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of Celebrex, Defendants failed to take any action to protect the health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

Celebrex and Cox-2 Studies Did Not Show Celebrex to be Safe

88. The defendants touted the Celebrex Long-Term Arthritis Safety Study ("CLASS") as the primary evidence to support its theory that Celebrex was safer for consumers that could not tolorate traditional NSAIDs in their gastrointestinal system. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

CLASS

89. The FDA Medical Officer Review of the CLASS data proves Celebrex is no more efficacious than other traditional NSAIDS and is harmful to consumers. See generally, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000 ("FDA CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only minimal information is available regarding Celebrex: "The only available data from a long term comparison of Celebrex to other NSAIDs came from the CLASS study...."

90. Pfizer misrepresented the data in CLASS by using biased authors. According to the *Washington Post* the CLASS authors were either employees of Pharmacia, Celebrex's manufacturer, or paid consultants of the company. Pfizer needed a study to

demonstrate that its Cox-2 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed to be that study. Unfortunately, the results of the completed study revealed the truth – Celebrex offered no gastrointestinal (GI) benefit. Instead of releasing the complete – 12-month – results from CLASS, Pfizer had only the first six months of data published in the Journal of American Medicine. JAMA 2000,48:1455-1460.

91. "After reviewing the full study, the FDA's arthritis advisory committee concluded that Celebrex offers no proven safety advantage over the two older drugs in reducing the risk of ulcer complications, said FDA spokesman Susan Cruzan." *Washington Post,* August 5, 2001. According to the FDA's review of the CLASS data: "celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored Celecoxib" (FDA CLASS Review)

92. According to an August 5, 2001 article in the *Washington Post*, editors of the Journal of the American Medical Association (JAMA) and other medical experts, "were flabbergasted" when they realized they had been duped by only being provided with the first six months of CLASS data. The Washington Post reported JAMA editors as saying: "When all of the data were considered, most of Celebrex's apparent safety advantage disappeared."

93. The "scientific double-cross" boosted sales. "[T]he JAMA article and editorial have likely contributed to Celebrex's huge sales. 'When the JAMA article comes out and confirms the hype, that probably has more impact than our labeling does,' said Robert J. Temple, director of medical policy at the FDA's Center for Drug Evaluation and Research." *Washington Post*, August 5, 2001.

94. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review, at 54. The increased number of adverse cardiovascular events in the Celebrex group were not surprising as they were also revealed in the original New Drug Application (NDA) submitted for Celebrex. "In

the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any does was cardiovascular." FDA CLASS Review at 78.

95. Public Citizen, a public watchdog organization, reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events was 1.4% in celecoxib (Celebrex) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the Celebrex was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

96. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor, Celebrex, caused a disproportionately and statistically significantly high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of Celebrex.

APC Trial

97. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the number of deaths from cardiovascular causes was significantly higher in the Celebrex group when compared to placebo. (0.1% placebo; 0.4% Celebrex 200mg; and 0.9% Celebrex 400mg). Id. at 1075.

98. The FDA Reported the APC data as follows[39]:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for Celebrex compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for Celebrex 200 mg twice daily and 3.4 Celebrex 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

99. The dosage noted in the study is important for two reasons: first, there

[39] April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

appears to be an association between dosage and the increase in adverse cardiovascular events. See generally, at 1077. Second, most patients increase dosage. Pfizer knew patients were increasing their dosages as noted in CLASS: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, Pfizer was aware of the dosage creep.

Other Celebrex Trials

100. Several other Celebrex trials also gave Defendants insight into the cardiovascular risks presented by Celebrex. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with Celebrex as compared to 2.7% for placebo.

101. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)"[40]. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo."[41]

Cox-2 Studies: VIGOR and APPROVe

102. Pfizer also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

VIGOR

103. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS

---

[40] *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe.
[41] Id.

Review at 78.

104. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

105. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of Cox-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including Defendants, were aware of these results.

APPROVe

106. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)[42]. *Public Citizen*, January 24, 2005, at 15. Despite the available Celebrex data and other information related to Vioxx, Pfizer never paused to re-evaluating the Celebrex data and studies.

[42] Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

107. The scientific data available during and after Celebrex's approval process made clear to Defendants that their formulation of Celebrex would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Celebrex consumers, alerting them to the need to do additional and adequate safety studies.

108. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing to humans " . . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

109. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

110. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of Celebrex did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take Celebrex. Therefore, Defendants' testing and studies were grossly inadequate.

111. Had Defendants done adequate testing prior to approval and "market launch," rather than the extremely short duration studies done on the small size patient base that was actually done the defendants' scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

112. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued Celebrex sales.

113. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

114. At the time Defendants manufactured, advertising, and distributed Celebrex to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAIDs.

J. Facts Regarding Defendants' Marketing and Sale of Celebrex

115. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiff, would not have purchased Celebrex, a more costly prescriptive drug, ineffective for its intended purposes.

116. On January 10, 2005 the FDA issued Pfizer a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 Celebrex and 2 Bextra] variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." This was not the Defendants first offense related to its Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting: "DDMAC has reviewed these promotional pieces and has determined that they are false or misleading because they contain unsubstantiated comparative claims, misrepresentations of Celebrex's safety profile, and are lacking in fair balance." Ultimately, on April 8, 2005, the New York Times reported the results of an FDA advisory panel: "The February advisory panel voted overwhelmingly that the company should never again advertise the drug [Celebrex]."

117. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive Celebrex as a safer and better drug than its other NSAIDs and, therefore, purchase Celebrex.

118. Defendants widely and successfully marketed Celebrex throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Celebrex in order to induce a widespread use and consumption. Celebrex was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

119. Despite knowledge of the dangers presented by Celebrex, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, Celebrex, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, Celebrex. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product, Celebrex, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

120. In an elaborate and sophisticated manner, Defendants aggressively marketed Celebrex directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Celebrex on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payors were compelled to add Celebrex to their formularies. Defendants' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Celebrex.

121. Defendants represented that Celebrex was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants promoted Celebrex as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

122. Celebrex possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, Celebrex was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

123. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved Celebrex for sale, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of Celebrex. Defendants' omission, suppression, and concealment of this important information enabled Celebrex to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

124. Consequently, Celebrex captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of Celebrex exceeded $2 billion, despite the significantly higher cost of Celebrex as compared to other pain relievers in the same family of drugs.

125. Because Defendants engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted Celebrex as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of Celebrex, Defendants were able to justify pricing Celebrex significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about

Celebrex, Defendants would not and could not have reaped the billions of dollars in Celebrex sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

126. The Defendants intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of Celebrex from Plaintiff, the public, the medical community, and the regulators. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of Celebrex, and prevented Plaintiff from obtaining all the material information that would be important to their decisions as reasonable persons to purchase, pay for, and/or use Celebrex.

127. Defendants' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use Celebrex; and caused Plaintiff's losses and damages as asserted herein.

128. Had Defendants done adequate testing prior to approval and "market launch," the defendants' scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

129. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued Celebrex sales.

130. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

131. At the time Defendants manufactured, advertising, and distributed Celebrex to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAID drugs.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF: Negligence

132. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

133. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Celebrex. This duty included the duty not to introduce a pharmaceutical drug, such as Celebrex, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

134. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug Celebrex.

135. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of Celebrex, including:

a. failing to use due care in the preparation and development of Celebrex to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

b. failing to use due care in the design of Celebrex to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

c. failing to conduct adequate pre-clinical testing and research to determine the safety of Celebrex;

d. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Celebrex;

e. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

f. failing to accompany Celebrex with proper warnings regarding all possible adverse side effects associated with the use of Celebrex;

g. failing to use due care in the manufacture, inspection, and labeling of Celebrex to prevent the aforementioned risk of injuries to individuals who used Celebrex;

h. failing to use due care in the promotion of Celebrex to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

i. failing to use due care in the sale and marketing of Celebrex to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. failing to use due care in the selling of Celebrex to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

k. failing to provide adequate and accurate training and information to the sales representatives who sold Celebrex;

l. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Celebrex; and

m. being otherwise reckless, careless and/or negligent.

136. Despite the fact that Defendants knew or should have known that Celebrex caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market Celebrex to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

137. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that Celebrex caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of Celebrex.

138. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

139. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

140. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

141. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF:
Strict Liability

142. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows:

143. At all times relevant to this action, Defendants were suppliers of Celebrex, placing the drug into the stream of commerce. Celebrex was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

144. Celebrex was unsafe for normal or reasonably anticipated use.

145. Celebrex was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. Celebrex was also defective and unreasonably dangerous in that the foreseeable risk of injuries from Celebrex exceeded the benefits associated with the design and/or formulation of the product.

146. Celebrex is unreasonably dangerous: a) in construction or composition; b) in design; c) because an adequate warning about the product was not provided; d) because it does not conform to an express warranty of the manufacturer about the product.

147. Celebrex as manufactured and supplied by Defendants was also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiff to the medication, testing which would have shown that Celebrex had the potential to cause serious side effects including the injuries suffered like the Plaintiff.

148. Celebrex as manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from Celebrex, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and advertising Celebrex; and, further, it continued to affirmatively promote Celebrex as safe and effective.

149. Celebrex was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective design of Celebrex, Plaintiff used Celebrex rather than other safer and cheaper NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.

150. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of Celebrex, especially the information contained in the advertising and promotional materials, did not accurately reflect the potential side effects of Celebrex.

151. Had adequate warnings and instructions been provided, Plaintiff would not have taken Celebrex, and would not have been at risk of the harmful side effects described herein.

152. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by Celebrex.

153. Plaintiff could not, through the exercise of reasonable care, have discovered Celebrex's defects or perceived the dangers posed by the drug.

154. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

155. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

156. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF:
Breach of Express Warranty

157. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

158. Defendants expressly represented to Plaintiff and other consumers and the medical community that Celebrex was safe and fit for its intended purposes, that it was of

merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

159. These warranties came in the form of:

a. Defendants' public written and verbal assurances of the safety and efficacy of Celebrex;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for Celebrex, which failed to warn of the risk of injuries inherent to the ingestion of Celebrex, especially to the long-term ingestion of Celebrex;

c. Verbal and written assurances made by Defendants regarding Celebrex and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing Celebrex during the period of Plaintiff's ingestion of Celebrex, and;

e. advertisements.

160. The documents referred to above were created by and at the direction of Defendants.

161. Defendants knew or had reason to know that Celebrex did not conform to these express representations in that Celebrex is neither as safe nor as effective as represented, and that Celebrex produces serious adverse side effects.

162. Celebrex did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

163. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

164. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related

expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

165. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

166. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF:
Breach of Implied Warranty

167. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

168. Defendants manufactured, distributed, advertised, promoted, and sold Celebrex.

169. At all relevant times, Defendants knew of the use for which Celebrex was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

170. Celebrex was not of merchantable quality and was not fit for its intended use, because it causes increased risk of TEN/SJS reactions and serious cardiovascular and cerebrovascular adverse events, including heart attacks, strokes and other serious and harmful adverse health effects.

171. Defendants breached the implied warranty that Celebrex was of merchantable quality and fit for such use in violation of Oklahoma law.

172. Defendants were aware that consumers, including Plaintiff, would use Celebrex for treatment of pain and inflammation and for other purposes.

173. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe Celebrex only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for Celebrex.

174. Celebrex reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

175. Defendants breached their implied warranty to consumers, including Plaintiff; Celebrex was not of merchantable quality or safe and fit for its intended use.

176. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

177. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

178. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF:
Fraudulent Misrepresentation & Concealment

179. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

180. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of Celebrex, and their intentional dissemination of promotional and marketing information about Celebrex for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about Celebrex's risks and harms to doctors and consumers.

181. Defendants made fraudulent affirmative misrepresentations with respect to Celebrex in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Celebrex had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that Celebrex was safer than other alternative medications.

182. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of Celebrex.

183. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that Celebrex had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

184. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Celebrex including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'

purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Celebrex in order to increase its sales.

185. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

186. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Celebrex.

187. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

188. Plaintiff's physician and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Celebrex in selecting Celebrex treatment.

189. Plaintiff and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

190. Had Plaintiff been aware of the increased risk of side effects associated with Celebrex and the relative efficacy of Celebrex compared with other readily available medications, Plaintiff would not have taken Celebrex as he did.

191. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

192. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

193. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)

194. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

195. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of Celebrex.

196. Plaintiff paid for Celebrex for the purpose of managing his pain safely and effectively.

197. Defendants have accepted payment from Plaintiff for the purchase of Celebrex.

198. Plaintiff did not receive the safe and effective pharmaceutical product for which he paid.

199. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented Celebrex to be.

200. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CLAIM FOR RELIEF
(Violations of State Consumer Fraud and Deceptive Trade Practices Acts)

201. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.

202. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Celebrex to Plaintiff.

203. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of all Oklahoma's consumer protection laws, identified below. Through its false, untrue and misleading promotion of Celebrex, Defendants induced Plaintiff to purchase and/or pay for the purchase of Celebrex. Defendants misrepresented the alleged benefits and characteristics of Celebrex; suppressed, concealed and failed to disclose material information concerning known adverse effects of Celebrex; misrepresented the quality of Celebrex as compared to much lower-cost alternatives; misrepresented and advertised that Celebrex was of a particular standard, quality or grade that it was not; misrepresented Celebrex in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have switched from Celebrex to another NSAID and/or chosen not to purchase and/or reimburse for purchases of Celebrex; advertised Celebrex with the intent not to sell it as advertised; and otherwise engaged in fraudulent and deceptive conduct.

204. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived and damaged Plaintiff and Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for purchases of Celebrex. Moreover, Defendants knowingly took advantage of Plaintiff who was reasonably unable to protect her interests due to ignorance of the harmful adverse effects of Celebrex. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiff and offends the public conscience.

205. Plaintiff purchased primarily for personal, family or household purposes.

206. As a result of Defendants' violative conduct, Plaintiff purchased and/or paid for purchases of Celebrex that were not made for resale.

207. Defendants engaged in unfair competition or deceptive acts or practices in violation of Oklahoma law.

208. As a proximate result of Defendants' misrepresentations and omissions, Plaintiff and Plaintiff have suffered ascertainable losses, in an amount to be determined at trial.

209. Throughout the period described in this Complaint, Defendants repeatedly engaged in intentional misconduct characterized by trickery, deceit and a wanton, willful, conscious and reckless disregard of the health, rights and interests of the Plaintiff, and, in so conducting itself, acted with oppression, fraud, and malice toward the Plaintiff. As a result of Defendants' indifference to and reckless disregard of the health and safety of Celebrex patients, they suffered both physical and economic harm, and all end-payors incurred economic damages. Accordingly, Defendants' conduct was highly reprehensible under controlling Supreme Court punitive damages authority, and Plaintiff is entitled to punitive and/or exemplary damages.

210. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

211. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

212. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

1. General damages in excess of the jurisdictional amount of this Court;

2. Consequential damages;

3. Disgorgement of profits;

4. Restitution;

5. Punitive and exemplary damages;

6. Pre-judgment and post-judgment interest as provided by law;

7. That the Court enter a judgment against each Defendant, jointly and severally, for all general and compensatory damages allowable to Plaintiff;

8. That the Court enter a judgment against each Defendant, jointly and severally, for all special damages allowable to Plaintiff;

9. That the Court enter a judgment against each Defendant serving to award Plaintiff punitive damages;

10. That the Court enter a judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiff under this Complaint;

11. That the costs of this action be cast upon Defendant; and

12. That the Court grant Plaintiff such further relief which the Court deems just and appropriate

13. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

14. Such other and further relief as the Court deems just and proper.

Dated: September 18, 2007

Respectfully submitted,

By: _____

B. Kristian W. Rasmussen, III, FL Bar No. 0229430
LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.
316 South Baylen Street, Suite 600 (32502)
P. O. Box 12308
Pensacola, Florida 32591
Telephone: (850) 435-7080
Facsimile: (850) 435-7020

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: September 18, 2007

Respectfully submitted,

By: _____

B. Kristian W. Rasmussen, III, FL Bar No. 0229430
LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.
316 South Baylen Street, Suite 600 (32502)
P. O. Box 12308
Pensacola, Florida 32591
Telephone: (850) 435-7080
Facsimile: (850) 435-7020

Attorneys for Plaintiff